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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/020,733	10/30/2001	D. Wade Walke	LEX-0263-USA	9776

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EXAMINER	
MOORE, WILLIAM W	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 10/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/020,733	WALKE ET AL.	
	Examiner	Art Unit	
	William W. Moore	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-4 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-4 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5 & 6 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Although a restriction requirement had been stated to Applicant's counsel during a telephone conversation on June 26, 2003, and a provisional election had been made at that time to prosecute an invention of claim 1, in part, and claim 2 wherein the amino acid sequence encoded by a claimed nucleic acid molecule is either of SEQ IDs NOs: 6 or 8, the requirement for restriction is hereby RESCINDED, and claims 1-4 are examined herein because a search conducted with SEQ ID NO:5 herein produced prior art relevant to each of the nucleic acid molecules encoding amino acid sequences of SEQ IDs NOs: 2, 4, 6 and 8 described by claims 1-4 herein.

Claim Rejections - 35 USC § 101

35 U.S.C. §101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-4 are rejected under 35 U.S.C. §101 because the claimed invention lacks patentable utility.

A claimed invention must posses a specific, substantial and credible *in vitro* or *in vivo* utility, but the instant application cannot identify any specific, substantial, utility for the invention described by the claims known to the inventors at the time the application was filed. It is agreed that the polypeptides having the amino acid sequences of SEQ IDs NOs:2, 4, 6 and 8 share a significant degree of amino acid sequence homology with other, prior art, human metalloproteases. Yet the polynucleotides described by claims 1-4 lack utility because the specification discloses no specific *in vitro* utility for an isolated nucleic acid sequence having the nucleotide sequences of any of SEQ IDs NOs:1, 3, 5 or 7, nor any disclosure of a specific *in vitro* utility for isolated nucleic acids with generic nucleotide sequences encoding the amino acid sequences of any of SEQ IDs NOs:2, 4, 6 and 8. Neither does the specification indicate any specific *in vivo* or *in vitro* utilities for

their encoded polypeptides having the amino acid sequences of any of SEQ IDs NOs:2, 4, 6 and 8. Although the specification proposes, at page 1, that "disclosed polynucleotides . . . can be used for diagnosis, drug screening, clinical trial monitoring, the treatment of diseases and disorders, and cosmetic or nutriceutical applications" these proposed utilities are not specific because there is no disclosure of any particular disease state or medical condition may or may not be diagnosed or treated, nor any disclosure of how to screen for drugs that may or may not affect any specific physiological function or physiological conditions, nor any disclosure of the specific nature of any kind of clinical trial to be monitored for any particular purpose, nor even a disclosure of the nature of any particular cosmetic or nutriceutical application of a disclosed metalloprotease.

Although the specification proposes, at pages 2 and 3, that the physiological function of the encoded metalloprotease products might be determined by constructing transgenic animals deficient in the expression of nucleic acid sequences encoding the amino acid sequences of any of SEQ IDs NOs:2, 4, 6 or 8, there is no disclosure of any specific physiological condition or state that might implicates the lack of function, or the aberrant function, of any of the metalloproteases encoded by SEQ ID NO:1, 3, 5, or 7, and there is no suggestion of any physiological or cellular function for any metalloprotease encoded by a claimed nucleic acid sequence. A method of use of a material for further research to determine, e.g., its specific biological role, thus identifying or confirming a "real world" context for its use, cannot be considered to be a "substantial utility". *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966). Mere allegations of a prospective, potential, utility cannot rise to the level of a credible assertion of a specific in vivo utility that is substantial. Indeed, the specification's diffuse assertions indicate the contrary, that Applicant knew no specific utility for any of the four disclosed metalloproteases encoded by a claimed nucleic acid sequence at the time the application was filed that would permit

an immediate use by the public of a disclosed nucleic acid sequence, or any use by the public of an expression vector or cell comprising a disclosed nucleic acid sequence.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4 are also rejected under 35 U.S.C. §112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Conclusion

While subject to rejections above under 35 U.S.C. §§101 and 112, first paragraph, for lack of utility and for lack of enablement as to use, claims 1-4 present no issues of enablement as to making, or of an indefinite description, under the first paragraph and second paragraphs of 35 U.S.C. §112 because the scope of the intended subject matter is clear and artisans can make the generic polynucleotides encoding the polypeptides of SEQ IDs NOs:2, 4, 6 and 8 of claim 1 and use them to recombinantly produce the encoded metalloproteases. Polynucleotides of claims 1-4 are free of the prior art made of record with Applicant's Information Disclosure Statements filed on March 15 and on April 21, 2002, because Ruben et al., WO 2000/073323, and the several, counterpart, published U.S. patent applications of Ruben et al. made of record herewith – US 2002/0165377, US 2002/0173640, and US 2002/0182702 – all commonly disclose a polynucleotide, SEQ ID NO:2 in each, having a nucleic acid sequence encoding a metalloprotease, SEQ ID NO:9 in each, comprising the first 901 amino acids of the 918-amino acid sequence of the metalloprotease of SEQ ID NO:4 herein but diverging therefrom at every one of the

subsequent 17 carboxyl-terminal amino acid positions, thus can neither disclose nor suggest a nucleic acid sequence encoding any of the metalloproteases of SEQ IDs NOs:2, 4, 6 or 8 herein. Applicant's cited Docherty et al., WO 97/09420, and the counterpart U.S. patent to Docherty et al., U.S. 5,883,241, made of record herewith, commonly disclose polynucleotides, the cDNA of their SEQ ID NO:1 and its internal open reading frame of SEQ ID NO:2, having a nucleic acid sequence encoding a metalloprotease, their SEQ ID NO:3, comprising the sequence of amino acids from position 176 through position 909, inclusive, of SEQ ID NO:6 herein, thus can neither disclose nor suggest a nucleic acid sequence encoding any of the metalloproteases of SEQ IDs NOs:2, 4, 6 or 8 herein.

Polynucleotides described by claims 1-4 are also free of the disclosures in the PCT publications of Yue et al. and Delegeane et al., respectively WO 2001/98468 and WO 2002/08396, made of record herewith. Yue et al. disclose a polynucleotide, their SEQ ID NO:37, having a nucleic acid sequence encoding a metalloprotease, their SEQ ID NO:16, comprising the sequence of amino acids from position 85 through position 963, inclusive, of the metalloprotease of SEQ ID NO:6 herein, thus can neither disclose nor suggest a nucleic acid sequence encoding any of the metalloproteases of SEQ IDs NOs:2, 4, 6 or 8 herein. Delegeane et al. disclose a polynucleotide, their SEQ ID NO:39, having a nucleic acid sequence encoding a metalloprotease, their SEQ ID NO:18, comprising the first 901 amino acids of the 918-amino acid sequence of the metalloprotease of SEQ ID NO:4 herein but diverging therefrom at every one of the subsequent 17 carboxyl-terminal amino acid positions, thus can neither disclose nor suggest a nucleic acid sequence encoding any of the metalloproteases of SEQ IDs NOs:2, 4, 6 or 8 herein.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is 703.308.0583. The examiner can normally be reached between 9:00AM and 5:30PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at 703.308.3804. The fax phone numbers for the organization where this application or proceeding is assigned are

703.308.4242 for regular communications and 703.308.0294 for After Final communications. The examiner's direct fax phone number is 703.746.3169. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703.308.0196.

William W. Moore
October 10, 2003

NASHAAT T. NASHED PHD.
PRIMARY EXAMINER